COMMENTARY

THE DOE'S ROLE IN ISOTOPE PRODUCTION

Hazel R. O'Leary

CUSTOMERS, STAKEHOLDERS and the public play a large and important role in helping the Federal Government maintain an effective, efficient program to produce and deliver isotopes. Recent events have shown how important their involvement can be. The passage of the Fiscal Year 1995 Federal Budget was a prime example; it enabled the Department to conduct the program without the need to recover all costs. Another key event was the decision by the Department, supported by funding from Congress, to establish a domestic source of ^{99}Mo, by far the most widely used medical isotope in the world today. I will discuss both of these events in detail. In doing so, I hope to encourage all isotope customers and stakeholders—especially the members of the nuclear medicine community—as well as the public to participate actively in addressing the issues affecting the availability of important isotopes in the United States.

A National Isotope Strategy

The development of isotope technology and its ongoing transfer to private industry is a major success story. Over the past 50 years, the Department of Energy and its predecessor agencies conducted this program as an adjunct of energy research, defense and power reactor development programs. As the range and uses of available isotopes has increased, applications have become interwoven with technical progress in medical research and practice as well as in other industries. The very existence of certain applications, such as medical imaging by PET, nondestructive testing, radiation sterilization and measuring the thickness of paper, are dependent on the ready availability of isotopes.

To realize the full range of societal benefits to be derived from isotope technologies, the Nation must continue to invest in the production and distribution of isotope products and services. This is particularly true of those isotopes for which current demands are small, erratic and unprofitable but which are vital to U.S. research and development. A 1993 Arthur Andersen & Company report to the Department emphasized this by stating: "The use of isotopes is thus important in innumerable medical as well as industrial and research and development activities generally considered critical to continuing improvements in U.S. industrial competitiveness and the quality of life."

The Department has two central missions for its Isotope Production and Distribution Program. These recognize the importance of pricing isotopes in a manner that assures their availability. First, the Department will produce and distribute certain radioisotopes and enriched stable isotopes for research and development purposes or medical diagnosis and therapy. Prices for these isotopes are set at a level designed to balance the interest in recovering costs on the one hand and *the national priority of meeting U.S. research needs and supporting our health care system on the other.* Second, the Department will continue to produce and distribute other radioisotopes and enriched stable isotopes for medical diagnostic, therapeutic and other useful applications on a full-cost recovery basis. These two missions are the basis of the Department's National Isotope Strategy.

The Department plans to implement this strategy by continuing to deliver products and services from our production facilities to serve a broad community of isotope users. In consultation with its customers, stakeholders and the public, the Department will identify isotopes needed for medical, industrial and research applications. This will include isotopes that are not currently available to support important research projects. The Department will first encourage private sector sources to produce these isotopes. If no private sector source is available, the Department will seek appropriated funding to produce selected, highly important isotopes. Our program to establish a backup source of ^{99}Mo is a case in point.

As an additional part of this strategy, we will address the changing status of isotope production at the Department's facilities. The production of isotopes as byproducts of other major departmental programs has worked well since 1946. Nevertheless, changing worldwide needs and increasingly restrictive Federal budgets are causing a dramatic change with isotope production evolving from a secondary to a primary facility mission. In addition, for certain isotopes, the use of departmental facilities—not primarily designed or dedicated to the production of research, industrial or medical isotopes— is inefficient and costly to the Department's customers and taxpayers. Therefore, the Department will continue to evaluate, in cooperation with its customers and stakeholders as appropriate, possible options for future isotope production facilities, such as our efforts to establish an expanded capability for the accelerator-produced isotopes.

The Challenges

The isotope community has made it clear that the Department will be looked upon as a major isotope producer, especially for reactor generated isotopes, well into the next century. The Department's program to produce isotopes, however, is facing a number of serious difficulties. A large portion of the operating costs for the facilities that currently produce isotopes are not borne by the Department's Isotope Program but by the Department's Offices of Energy Research, Defense Programs and Naval Reactors—the primary sponsors of these facilities. These primary sponsors have each cut back their funding substantially, leaving the Isotope Program, by default, to pay for a larger share of facility operating costs.

In addition, the Department's facilities used for isotope production are old. Age-related degradation must be addressed now

to assure their integrity and safety of operations. What's more, these facilities were not specifically designed to produce isotopes economically. Therefore, isotope production costs are generally high, and operating costs are expected to grow unless capital improvements in these facilities are made.

The private sector's reluctance to invest in the production of some isotopes, especially those produced in operating nuclear reactors, is another problem facing the Isotope Program. Furthermore, market prices for many isotopes are currently too low to justify private sector sponsorship of nuclear reactors, large accelerators and their associated support facilities. In addition, a lack of ability to predict demand for specific isotopes in potential isotope-related technology applications deters investment. One example is the North American availability of ^{99}Mo, which will be discussed later in this commentary.

Lastly, there is a dwindling educational base for people skilled in the basic areas of production and use of isotopes. Undergraduate and graduate programs for radiopharmaceutical chemistry, nuclear chemistry, accelerator physics and nuclear engineering have been disappearing from U.S. universities and colleges for the last 20 years. The nuclear medicine community, as well as the public, must be involved in overcoming these challenges.

The Status of Isotope Availability

From 1954 until 1989, production and distribution of isotopes by the Department and its predecessor agencies were supported by two sources: revenues from the sale of isotopes and related services and appropriations for departmental activities such as weapons production and energy research. The cost basis for the distribution of isotopes and isotope services was dictated by the Atomic Energy Act of 1954. The act authorized the distribution, sale, loan or lease of isotopes with or without charge. This was provided that when isotopes were distributed for a charge it would be done on an equitable basis providing reasonable compensation to the Government, not discouraging the use of isotopes or the development of supply sources independent of the Government and encouraging research and development.

In 1989, two events had significant impacts on the Department's Isotope Program and the availability of isotopes in this country. The first was the enactment of Public Law 101-101 that required the Department's Isotope Program to be financially self-sufficient. This new need for full-cost recovery narrowed the range of isotopes produced by the Department, forcing us to concentrate on high-volume isotopes with profit potential. This, in turn, led to increasing fees for research users to cover program expenses. Despite substantial efforts to operate the Isotope Program on a full-cost recovery basis, revenues from sales never met costs. Regrettably, this also disrupted the availability of isotopes, especially those needed for research.

The second event was the decision by the only U.S. producer of ^{99}Mo to cease production. ^{99}Mo is a reactor-produced isotope that is the parent isotope of ^{99m}Tc, the most widely used medical isotope in the world. Prior to 1989, there were two commercial sources of ^{99}Mo in North America. The first was Cintichem, the commercial operator of a reactor in Tuxedo, New York. With this reactor, the company produced almost 50% of the U.S. market requirement for ^{99}Mo. The other producer, Nordion International of Canada, was—and still is—dependent on an aging reactor operated by Atomic Energy of Canada Limited, the NRU, to produce ^{99}Mo.

In 1989, Cintichem was faced with an aging reactor facility that required substantial upgrading to meet contemporary Federal regulatory requirements. Cintichem decided to shut down ^{99}Mo production rather than make the financial commitment to reinstate production even though the demand for ^{99}Mo was growing. This left Nordion—using the aging NRU reactor—as the only North American source of ^{99}Mo.

The Nuclear Medicine Community and the Public

Isotope availability thus became a heated topic in the early 1990s, especially in the area of research isotopes and ^{99}Mo for medical applications. This issue was the topic of many meetings held at several professional conferences, including the annual meetings of the Society of Nuclear Medicine (SNM). Scores of letters from the nuclear medicine community expressing concern over the availability of isotopes were sent to Congress and Administration officials. In addition, three congressional hearings were held on isotope production and distribution between 1992 and 1993, with hundreds of pages of testimony submitted by key professional organizations—including the SNM.

As a direct result of the isotope community educating the public and providing credible information to decision makers, the fiscal year 1995 appropriation legislation directly addressed the isotope profitability and availability issues. First, the legislation allows production and distribution of isotope products and services to meet the interests of U.S. research needs with appropriated funds. Second, the legislation provides funding to designate an existing Department of Energy reactor to become a backup source for ^{99}Mo production by fiscal year 1996.

The Future Role of Government

The Department of Energy will continue to deliver isotope goods and services that contribute to the health, well-being and quality of life. In cooperation with its customers, stakeholders and the public, the Department has established an isotope policy which addresses the two needs associated with isotope availability: the need to support the research and development community with isotopes for which there are no other reliable supplies; and the need to ensure a reliable and competitive supply of isotopes for which an infrastructure and market have been developed.

The Federal Government will continue to play a significant role in the production and distribution of isotopes. What the role will be, however, depends a great deal on isotope customers and stakeholders—such as the nuclear medicine community—and the public making their views and concerns known to the Department and Congress.

Hazel R. O'Leary

Hazel R. O'Leary is the Secretary of Energy.